AUG 14 2009

510(k) Summary

K091288

[As required by section 807.92(c)]

1. Submitter:
   Microtek International, Inc.
   6, Industry East Road 3, Science-Based Industrial Park, Hsinchu, 30077, Taiwan.
   TEL: +886-3-5772155
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2. Official Correspondent:
   Mr. George Sun

3. Date of 510(k) Submittal: 29. April, 2009

4. Device Trade Name
   Medi-6000 Medical Image Digitizer

5. Common Name: Film digitizer

6. Classification Name:
   Image digitizer was classified in class II (21 CFR 892.2030)

7. Device Product Code:
   LMA

8. Predicate Device:
   Manufacturer: Howtek Incorporated
   Device name: Film digitizer
   Model name: Fulcrum
   510(k) No.: K021949

   Manufacturer: VIDAR Systems Corporation
   Device name: X-ray film digitizer
   Model name: P111, TeleRADPRO, VXR-12 plus
   510(k) No.: K993597

9. Device Description:
   The Medi-6000 is a digitizer that can easily transfer x-ray films into a digital format for patients, hospitals, and office records. It can capture

details in bright and dark areas of x-ray films and provide the medical professionals a convenient method to digitize the roentgenogram for the electric data storage.

10. Intended Use:

The Medi-6000 consists of a transparency film digitizer and paper CCD scanner that is used to digitize radiographs or X-ray film as well as paper reports or doctor's orders. When the Medi-6000 is used to digitize radiographic films, the digital image is intended for use in primary, secondary and over reading applications. The target users of the device are medical professionals or trained staffs.

11. Technological Characteristics:

The Medi-6000 with a high optical resolution of 600 dpi, a dynamic range of 4.0 Dmax, and the 16-bit grayscale, the Medi-6000 allows users to get better image details in just seconds.

12. Performance Testing:

The performance testing results for the Medi-6000 digitizer demonstrated that the device meets its intended use specifications and therefore meets the requirements necessary for its intended use as a component of a PAC or Teleradiology system.

13. Substantial Equivalence to Predicate Device:

Medi-6000 is substantially equivalent to Fulcrum and P111, TeleRADPRO, and VXR-12 plus. Medi-6000 employs the resolution values same as that of Fulcrum, and better than P111, TeleRADPRO, and VXR-12 plus. Comparison table of the principal characteristics of these three devices is shown in the Section II and specification data for the Medi-6000 is included in Section I-3.

14. Conclusions:

In terms of intended use, construction, function, safety, operating environmental conditions and effectiveness of the Medi-6000 film digitizer is substantially equivalent to the predicate devices used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Microtek International, Inc.
% Mr. Hui-chen Kai, Supervisor
Electronics Testing Center, Taiwan
No. 8, Lane 29, Wenming Rd.
Guisan, Taoyuan, 33383
TAIWAN

AUG 14 2009

Re: K091288
Trade/Device Name: Medi-6000 Medical Image Digitizer
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: LMA
Dated: July 17, 2009
Received: July 22, 2009

Dear Mr. Hui-chen Kai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Not known
K091288

Device Name: Medi-6000 Medical Image Digitizer

Indications For Use:
The Medi-6000 consists of a transparency film digitizer and paper CCD scanner that is used to digitize radiographs or X-ray film as well as paper reports or doctor's orders. When the Medi-6000 is used to digitize radiographic films, the digital image is intended for use in primary, secondary and over reading applications. This device is not to be used for primary image diagnosis in mammography. The target users of the device are medical professionals or trained staffs.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K091288

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